

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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MARY P. DORSEY, Individually and as	:
Administrator of the Estate of James Dorsey,	:
	:
Plaintiff,	:
	:
- against -	: No. 05-CV-10639 (RCL)
	:
PFIZER, INC., WARNER LAMBERT	: ANSWER
COMPANY, and PARKE-DAVIS, a division	:
of Warner-Lambert Company,	:
	:
Defendants.	:
	:
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Defendants Pfizer Inc. ("Pfizer"), Warner-Lambert Company ("Warner-Lambert"), and Parke-Davis, a division of Warner-Lambert Company ("Parke-Davis") (collectively, "Defendants"), by their undersigned counsel, answer Plaintiff's Complaint as follows:

I. Introduction

Deny the allegations in the Introduction, except admit that Warner-Lambert Company LLC agreed to plead guilty to two counts of violating the federal Food, Drug and Cosmetic Act, as set forth in an Information dated May 13, 2004, and refer to that document for its contents.

II. Parties

1. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1, and therefore deny same.

2. Deny the allegations in paragraph 2 as stated, except admit that Pfizer Inc. is a Delaware corporation with corporate headquarters in New York, New York, and that it has a registered agent in Boston, Massachusetts.

3. Deny the allegations in paragraph 3 as stated, except admit that Warner-Lambert Company was a Delaware corporation with corporate headquarters in Morris Plains, New Jersey until December 31, 2002, when it was converted into a Delaware limited liability company known as Warner-Lambert Company LLC.

4. Deny the allegations in paragraph 4.

III. Jurisdiction and Venue

5. Paragraph 5 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 5.

6. Paragraph 6 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 6.

7. Paragraph 7 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 7.

IV. Facts Common to All Counts

8. Paragraph 8 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 8, except admit that Pfizer is engaged in the business of manufacture and sale of pharmaceutical products; that Pfizer and Warner-Lambert merged in June, 2000; and that Parke-Davis was a division of Warner-Lambert at the time of the merger.

9. Deny the allegations in paragraph 9, except admit that Pfizer has marketed and sold Neurontin since June 2000, and that until approximately June 2000, the Parke-Davis division of Warner-Lambert marketed and sold Neurontin.

10. Deny the allegations in paragraph 10, except admit that until June 2000, the Parke-Davis division of Warner-Lambert was engaged in the development, manufacture,

promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States, and that it had pharmaceutical manufacturing facilities in Puerto Rico.

11. Paragraph 11 does not allege facts to which a response is required and states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 11.

12. Paragraph 12 does not allege facts to which a response is required and states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 12.

13. Paragraph 13 does not allege facts to which a response is required and states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 13.

14. Paragraph 14 does not allege facts to which a response is required and states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 14.

15. Paragraph 15 does not allege facts to which a response is required and states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 15.

16. Paragraph 16 does not allege facts to which a response is required and states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 16.

17. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3 (h)(4) and (5). In that application, WARNER-LAMBERT sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy.

18. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Information as the "Approved Use."

19. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

Because WARNER-LAMBERT had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the Approved Use.

20. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

21. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

As described in this Information, from at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses.

22. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of these Unapproved Uses during the time period addressed in this Information. Of these Unapproved Uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in this Information.

23. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23, and therefore deny same.

24. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24, and therefore deny same.

25. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25, and therefore deny same.

26. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26, and therefore deny same.

27. Deny the allegations in paragraph 27, except deny knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's illnesses and the belief of Plaintiff's physicians and therefore deny same.

28. Deny the allegations in paragraph 28 as stated, except admit that Neurontin has never been approved by the FDA for bipolar disorder.

29. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29, and therefore deny same.

30. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30, and therefore deny same.

31. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31, and therefore deny same.

32. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 32, and therefore deny same.

33. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33, and therefore deny same.

34. Deny the allegations in paragraph 34, except deny knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's husband and therefore deny same.

35. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35, and therefore deny same.

36. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36, and therefore deny same.

37. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37, and therefore deny same.

38. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38, and therefore deny same.

39. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39, and therefore deny same.

40. Deny the allegations in paragraph 40 as stated, except admit that in December 1993, the FDA approved Neurontin for labeling as safe and effective for adjunctive therapy in the treatment of partial seizures in patients with epilepsy.

41. Deny the allegations in paragraph 40 as stated, except admit that in December 1993, the FDA approved Neurontin for labeling as safe and effective at dosages of 900 to 1800 milligrams per day.

42. Deny the allegations in paragraph 42, and refer to Warner-Lambert's patent filings for their contents.

43. Deny the allegations in paragraph 43, except refer to Warner-Lambert's patent filings for their contents.

44. Deny the allegations in paragraph 44, except refer to Warner-Lambert's patent filings for their contents.

45. Deny the allegations in paragraph 45 as stated, except admit that Defendants never sought FDA approval for the treatment of mania, bipolar, anxiety or panic.

46. Deny the allegations in paragraph 46, except deny knowledge or information sufficient to form a belief as to the number of epileptics in the United States and therefore deny same.

47. Deny the allegations in paragraph 47.

48. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

In or about the fall of 1995, WARNER-LAMBERT's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

49. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

Certain of WARNER-LAMBERT's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

50. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these Unapproved Uses.

51. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

52. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

53. Deny the allegations in paragraph 53.

54. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

55. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

In or about July of 1995 WARNER-LAMBERT's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a WARNER-LAMBERT Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

56. Deny the allegations in paragraph 56.

57. Deny the allegations in paragraph 57.

58. Deny the allegations in paragraph 58.

59. Deny the allegations in paragraph 59.

60. Deny the allegations in paragraph 60.

61. Deny the allegations in paragraph 61.

62. Deny the allegations in paragraph 62.

63. Deny the allegations in paragraph 63.

64. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

In October, 1995, a member of WARNER-LAMBERT's Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month

period, was for off-label use of Neurontin. Nine were for pain and one was for reflex-sympathetic dystrophy, a painful nerve damage syndrome.

65. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

66. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

67. Deny the allegations in paragraph 67.

68. Deny the allegations in paragraph 68.

69. Deny the allegations in paragraph 69.

70. Deny the allegations in paragraph 70, and further deny knowledge or information

sufficient to form a belief as to the percentage of Neurontin prescribed for non-approved uses.

71. Deny the allegations in paragraph 71.

72. Deny the allegations in paragraph 72.

73. Deny the allegations in paragraph 73.

74. Deny the allegations in paragraph 74.

75. Deny the allegations in paragraph 75.

76. Deny the allegations in paragraph 76.

77. Deny the allegations in paragraph 77.

78. Deny the allegations in paragraph 78.

79. Deny the allegations in paragraph 79.

80. Deny the allegations in paragraph 80.

81. Deny the allegations in paragraph 81.

82. Deny the allegations in paragraph 82.

83. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

84. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between \$1,500 and \$2,000.

85. Deny the allegations in paragraph 85.

86. Deny the allegations in paragraph 86.

87. Deny the allegations in paragraph 87.

88. Deny the allegations in paragraph 88.

89. Deny the allegations in paragraph 89.

90. Deny the allegations in paragraph 90.

91. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

92. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

93. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

94. Deny the allegations in paragraph 94.

95. Deny the allegations in paragraph 95.

96. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

From August 1-5, 1996, WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics.

WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

97. Deny, except refer to the content of the Information and state that on or about

May 13, 2004 Warner-Lambert Company LLC admitted that:

During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen “consultants” and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on WARNER-LAMBERT’s behalf at prior meetings. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

Defendants specifically deny the remaining allegations in paragraph 97.

98. Deny the allegations in paragraph 98.

99. Deny the allegations in paragraph 99.

100. Deny the allegations in paragraph 100.

101. Deny the allegations in paragraph 101.

102. Deny the allegations in paragraph 102.

103. Deny the allegations in paragraph 103.

104. Deny the allegations in paragraph 104.

105. Paragraph 105 does not allege facts to which a response is required, and

Defendants therefore deny the allegations in paragraph 105.

106. Deny the allegations in paragraph 106.

107. Deny the allegations in paragraph 107.

108. Deny the allegations in paragraph 108.

109. Deny the allegations in paragraph 109.

110. Deny the allegations in paragraph 110.

- 111. Deny the allegations in paragraph 111.
- 112. Deny the allegations in paragraph 112.
- 113. Deny the allegations in paragraph 113.
- 114. Deny the allegations in paragraph 114.
- 115. Deny the allegations in paragraph 115.
- 116. Deny the allegations in paragraph 116.
- 117. Deny the allegations in paragraph 117.
- 118. Deny the allegations in paragraph 118.
- 119. Deny the allegations in paragraph 119.
- 120. Deny the allegations in paragraph 120.
- 121. Deny the allegations in paragraph 121.
- 122. Deny the allegations in paragraph 122.
- 123. Deny the allegations in paragraph 123.
- 124. Deny the allegations in paragraph 124 except admit that Warner-Lambert conducted a Phase IV trial known as STEPS.
- 125. Deny the allegations in paragraph 125.
- 126. Deny the allegations in paragraph 126.
- 127. Deny the allegations in paragraph 127.
- 128. Deny the allegations in paragraph 128.
- 129. Deny the allegations in paragraph 129, except admit that physicians who participated in the STEPS study received payment for participating in the study.
- 130. Deny the allegations in paragraph 130.
- 131. Deny the allegations in paragraph 131.

- 132. Deny the allegations in paragraph 132.
- 133. Deny the allegations in paragraph 133.
- 134. Deny the allegations in paragraph 134.
- 135. Deny the allegations in paragraph 135.
- 136. Deny the allegations in paragraph 136.
- 137. Deny the allegations in paragraph 137.
- 138. Deny the allegations in paragraph 138.
- 139. Deny the allegations in paragraph 139.
- 140. Deny the allegations in paragraph 140.
- 141. Deny the allegations in paragraph 141.
- 142. Deny the allegations in paragraph 142.
- 143. Deny the allegations in paragraph 143.
- 144. Deny the allegations in paragraph 144.
- 145. Deny the allegations in paragraph 145.
- 146. Deny the allegations in paragraph 146.
- 147. Deny the allegations in paragraph 147.
- 148. Deny the allegations in paragraph 148.
- 149. Deny the allegations in paragraph 149.
- 150. Deny the allegations in paragraph 150.
- 151. Deny the allegations in paragraph 151.
- 152. Deny the allegations in paragraph 152.
- 153. Deny the allegations in paragraph 153.
- 154. Deny the allegations in paragraph 154.

155. Paragraph 155 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 155.

156. Paragraph 156 does not allege facts to which a response is required, and Defendants therefore deny the allegations in paragraph 156.

157. Deny the allegations in paragraph 157.

158. Deny the allegations in paragraph 158.

159. Deny the allegations in paragraph 159.

160. Deny the allegations in paragraph 160.

161. Deny the allegations in paragraph 161.

162. Deny the allegations in paragraph 162.

163. Deny the allegations in paragraph 163.

164. Deny the allegations in paragraph 164.

165. Deny the allegations in paragraph 165.

166. Deny the allegations in paragraph 166.

167. Deny the allegations in paragraph 167.

168. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated: "What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin ... When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do." One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

169. Deny, except refer to the content of the Information and state that on or about May 13, 2004 Warner-Lambert Company LLC admitted that:

WARNER-LAMBERT employed “medical liaisons” who were presented to physicians as employees of the company’s Medical and Scientific Affairs Department.

170. Deny the allegations in paragraph 170.

171. Deny the allegations in paragraph 171.

172. Deny the allegations in paragraph 172.

173. Deny the allegations in paragraph 173.

174. Deny the allegations in paragraph 174.

175. Deny the allegations in paragraph 175.

176. Deny the allegations in paragraph 176.

177. Deny knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 177, and therefore deny same.

178. Deny the allegations in paragraph 178.

179. Paragraph 179 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 179.

180. Paragraph 180 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 180.

181. Paragraph 181 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 181.

182. Deny the allegations in paragraph 182.

183. Deny the allegations in paragraph 183.

184. Deny the allegations in paragraph 184.

185. Deny the allegations in paragraph 185.

186. Deny the allegations in paragraph 186.

187. Deny the allegations in paragraph 187.

V. Causes of Action

COUNT I

188. Repeat each and every response to the allegations in paragraphs 1 through 187.

189. Paragraph 189 states a legal conclusion to which no response is required, and Defendants therefore deny the allegations in paragraph 189.

190. Deny the allegations in paragraph 190.

191. Deny the allegations in paragraph 191, except admit that on January 14, 2005, Defendants received a letter from Plaintiff's counsel with a subject line reading "Letter of Demand Pursuant to Mass. G.L. 93A."

192. Deny the allegations in paragraph 192, except admit that Defendants received the letter on January 14, 2005 and that the above captioned action was filed on April 1, 2005.

193. Deny the allegations in paragraph 193, except refer to Defendants' response to the demand letter for its contents.

194. Deny the allegations in paragraph 194, except admit that Defendants were engaged in trade or commerce within the Commonwealth of Massachusetts.

195. Deny the allegations in paragraph 195.

196. Deny the allegations in paragraph 196.

197. Deny the allegations in paragraph 197.

COUNT II

198. Repeat each and every response to the allegations in paragraphs 1 through 197.

199. Deny the allegations in paragraph 199.

200. Deny the allegations in paragraph 200.

201. Deny the allegations in paragraph 201.

202. Deny the allegations in paragraph 202.

COUNT III

203. Repeat each and every response to the allegations in paragraphs 1 through 202.

204. Admit that until approximately June 2000 Warner-Lambert manufactured and sold Neurontin, and since approximately June 2000 Pfizer has manufactured and sold Neurontin.

205. Deny the allegations in paragraph 205.

206. Deny the allegations in paragraph 206.

207. Deny the allegations in paragraph 207.

208. Deny the allegations in paragraph 208.

209. Deny the allegations in paragraph 209.

210. Deny the allegations in paragraph 210.

COUNT IV

211. Repeat each and every response to the allegations in paragraphs 1 through 210.

212. Admit that until approximately June 2000 Warner-Lambert manufactured and sold Neurontin, and since approximately June 2000 Pfizer has manufactured and sold Neurontin.

213. Deny the allegations in paragraph 213.

214. Deny the allegations in paragraph 214.

215. Deny the allegations in paragraph 215.

216. Deny the allegations in paragraph 216.

217. Deny the allegations in paragraph 217.

COUNT V

- 218. Repeat each and every response to the allegations in paragraphs 1 through 217.
- 219. Deny the allegations in paragraph 219.
- 220. Deny the allegations in paragraph 220.
- 221. Deny the allegations in paragraph 221.

COUNT VI

- 222. Repeat each and every response to the allegations in paragraphs 1 through 222.
- 223. Deny the allegations in paragraph 223.
- 224. Deny the allegations in paragraph 224.
- 223. Deny the allegations in the second paragraph 223.
- 224. Deny the allegations in the second paragraph 224.

COUNT VII

- 225. Repeat each and every response to the allegations in paragraphs 1 through 224.
- 226. Deny the allegations in paragraph 226.
- 227. Deny the allegations in paragraph 227.
- 228. Deny the allegations in paragraph 228.

COUNT VIII

- 229. Repeat each and every response to the allegations in paragraphs 1 through 228.
- 230. Deny the allegations in paragraph 230.
- 231. Deny the allegations in paragraph 231.
- 232. Deny the allegations in paragraph 232.

COUNT IX

- 233. Repeat each and every response to the allegations in paragraphs 1 through 232.

234. Deny the allegations in paragraph 234.

235. Deny the allegations in paragraph 235.

COUNT X

236. Repeat each and every response to the allegations in paragraphs 1 through 235.

237. Deny the allegations in paragraph 237.

238. Deny the allegations in paragraph 238.

239. Deny the allegations in paragraph 239.

240. Deny the allegations in paragraph 240.

COUNT XI

241. Repeat each and every response to the allegations in paragraphs 1 through 241.

242. Deny the allegations in paragraph 242.

243. Deny the allegations in paragraph 243.

COUNT XII

244. Repeat each and every response to the allegations in paragraphs 1 through 243.

245. Deny the allegations in paragraph 245.

246. Deny the allegations in paragraph 246.

SEPARATE AND AFFIRMATIVE DEFENSES

FIRST DEFENSE

To the extent Plaintiff's claim under Chapter 93A seeks or encompasses damages other than damages incurred directly and solely by Plaintiff or damages that are not compensable under Chapter 93A, the claim will not lie.

SECOND DEFENSE

By failing to allege a loss of money or property, Plaintiff has failed to state a claim under Chapter 93A.

THIRD DEFENSE

Plaintiff's claim under Chapter 93A will not lie because she has not alleged and cannot establish that she suffered a loss of money or property as a direct and proximate result of any unfair or deceptive trade practices or acts by Defendants.

FOURTH DEFENSE

Plaintiff's claims for punitive damages will not lie under Massachusetts law.

FIFTH DEFENSE

Plaintiff's claim for unjust enrichment will not lie under Massachusetts law.

SIXTH DEFENSE

Plaintiff has failed to state a claim for intentional infliction of emotional distress.

SEVENTH DEFENSE

Plaintiff's claim for loss of consortium will not lie under Massachusetts law.

EIGHTH DEFENSE

Plaintiff's claims for equitable relief in the form of restitution and/or disgorgement of profits will not lie under Massachusetts law.

NINTH DEFENSE

Plaintiff's negligence claims are barred or limited to the extent Plaintiff's own negligent acts, conduct, and/or omissions constituted the cause of her alleged injuries and her own negligence was greater than the negligence of any other person or entity.

TENTH DEFENSE

Plaintiff's claims are barred to the extent Plaintiff's damages, if any, were caused by a third party over whom or which Defendants had no control and for whom or which Defendants are not responsible.

ELEVENTH DEFENSE

Plaintiff's claims entitled "Strict Product Liability - Failure to Warn and False Advertising" and "Strict Product Liability - Defective Design/Manufacturing" are preempted by federal law.

TWELFTH DEFENSE

Plaintiff's alleged damages, if any, were the result, if at all, of a superseding and intervening cause for which Defendants are not responsible.

THIRTEENTH DEFENSE

Plaintiff's product liability and breach of warranty claims are barred to the extent Plaintiff violated a duty to act reasonably with respect to the product in question and her violation of the duty caused her alleged injury.

FOURTEENTH DEFENSE

Defendants were entitled to rely on the independent judgment of Plaintiff's physician(s) with regard to the prescription, distribution, and use of the product in question, and, accordingly, Defendants are not liable to Plaintiff.

FIFTEENTH DEFENSE

Plaintiff's claims for breach of warranties will not lie to the extent Plaintiff failed to give sufficient and timely notice of the alleged breaches.

SIXTEENTH DEFENSE

Plaintiff's claims are time-barred.

SEVENTEENTH DEFENSE

Plaintiff has not adequately alleged, and cannot establish, that the injuries of which she complains were caused by the product in question or were the direct and proximate result of any action or omission of Defendants.

EIGHTEENTH DEFENSE

Plaintiff has not alleged, and cannot establish, an actionable misrepresentation, scienter, reliance, or causation.

NINETEENTH DEFENSE

Plaintiff has failed to plead fraud with sufficient particularity.

TWENTIETH DEFENSE

Plaintiff has not alleged, and cannot establish, that her physician(s) prescribed the product in question to her based on an actionable misrepresentation on which the physician(s) reasonably relied.

TWENTY-FIRST DEFENSE

Plaintiff's claims are barred in whole or in part under the First Amendment to the United States Constitution and its Massachusetts counterpart.

TWENTY-SECOND DEFENSE

Plaintiff's claims are barred or limited to the extent she or her agents failed to mitigate damages.

TWENTY-THIRD DEFENSE

Plaintiff's claim under Chapter 93A will not lie because it arises out of alleged acts or practices that, assuming they occurred, did not occur primarily and substantially within the Commonwealth of Massachusetts.

WHEREFORE, Defendants demand judgment dismissing Plaintiff's claims with prejudice, awarding them costs, and providing for such other and further relief as is just and appropriate.

Dated: May 23, 2005

PFIZER INC., WARNER-LAMBERT
COMPANY, and PARKE-DAVIS, a Division of
Warner-Lambert Company,

By their attorneys,

s/David B. Chaffin
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